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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,352	12/14/2001	Jens Mattsson	53631-65307	3692

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EXAMINER	
NAVARRO, ALBERT MARK	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 01/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/914,352	Applicant(s) MATTSSON, JENS	
	Examiner Mark Navarro	Art Unit 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 December 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: _____.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See attached.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

ADVISORY ACTION

Applicants arguments filed December 16, 2005 have been received and entered. Claims 2-3, 8-9, 12-13, 16 and 27 have been canceled. Consequently, claims 1, 4, 6-7, 10-11, 14-15, 17-26, and 28-30 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 4, 6-7, 10-11, 14-15, 17, 22-26, 28 and 30 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are asserting that page 10, lines 5-28 of the specification, set forth of an isolated mite-derived protein from Sarcoptes scabiei (MSA1). Applicants further assert that the present disclosure further teaches that MSA1 corresponds to a native 164 kDa protein.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that page 10, lines 5-28 of the specification, set forth of an isolated mite-derived protein from Sarcoptes scabiei (MSA1), and that it is a 164 kDa protein, clearly more than just a single fragment. However, Applicants are respectfully directed back to the claims, which recite "An isolated mite protein comprising ***amino acids 1-83 of SEQ ID NO: 2***." Contrary to Applicants arguments, the claims are clearly directed to a "fragment" of a protein. Applicants specification is silent as to the nature or number of additional amino acids N terminus or C terminus of this specific fragment to form a full length protein. These additional amino

acids will have a profound impact on the activity of the full length protein. Without describing the nature of these regions, Applicants written description satisfies only the precisely recited fragment, i.e., consisting of amino acids 1-83 of SEQ ID NO: 2.

Finally, Applicants assert that the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. However, this is the precise basis of the written description rejection. Applicants have disclosed only a fragment of a full length protein. Without disclosure of the full length protein, Applicants written description is only adequately described for the identified fragment. *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a ***representative number*** of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. (Emphasis added). In contrast, Applicants have disclosed only one "consisting of" fragment of a protein, as such the written description requirement is found to be lacking for claims which encompass the full length protein.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 20-21 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an immunogenic composition consisting of SEQ ID NO:

2 does not reasonably provide enablement for methods of ***treatment*** comprising administering compositions consisting of SEQ ID NO: 2 is maintained.

Applicants are asserting that the specification teaches that the proteins of the present invention comprise amino acids from the MSA1, which corresponds to a native protein, which provides a rapid immunogenic response in animals. Thus Applicant believes that the present disclosure provides the proper guidance to utilize the claimed compositions for the treatment of a disease associated with mites.

Applicants arguments have been fully considered but are not found to be fully persuasive.

As set forth previously by Plotkin et al, those of skill in the art recognize that it is unpredictable whether a single protein derived from a pathogen will elicit protective immunity. This is the type of immunity required by Applicants claims 20-21, i.e., for the ***treatment*** of a disease associated with mites. Thus, Factors 1, 4, 5 and 7 are all addressed by this teaching. This teaching is simply not limited to recombinant DNA vaccines as argued by Applicants. Plotkin et al clearly set forth that one of the key problems of vaccine development is identifying the "protein component" that can elicit protective antibodies. Any protein can elicit an antibody under the right conditions. However, only "protective antibodies" will be capable of providing any degree of protection or treatment therapy. Applicants are no doubt well aware, that there are numerous antibodies to numerous HIV proteins, none of which offer any protection to HIV infection or eradication.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the

quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

The specification provides insufficient guidance of how to use the claimed polypeptides as a pharmaceutical for the treatment of disease. It is well recognized in the art that it is unclear whether a single protein derived from a pathogen will elicit protective immunity. Ellis, R.W. (see Chapter 29 of "VACCINES" [Plotkin, S.A et al.,(ed.), published by W.B. Saunders Company (Philadelphia) in 1988, especially page 571, 2nd full paragraph] exemplifies this problem in the recitation that "The key to the problem (of vaccine development) is the identification of that protein component of a virus or microbial pathogen that itself can elicit the production of protective antibodies ...and thus protect the host against attack by the pathogen." Furthermore, Applicants specification provides no working examples of any treatment. (Factors 1 and 3).

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to producing and using the proteins encompassed in the scope of the claims one skilled in the art would be forced into undue experimentation in order to practice broadly the claimed invention.

For reasons of record, as well as the reasons set forth above this rejection is maintained.

Claims 18-19 and 29 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Navarro
Primary Examiner
December 30, 2005